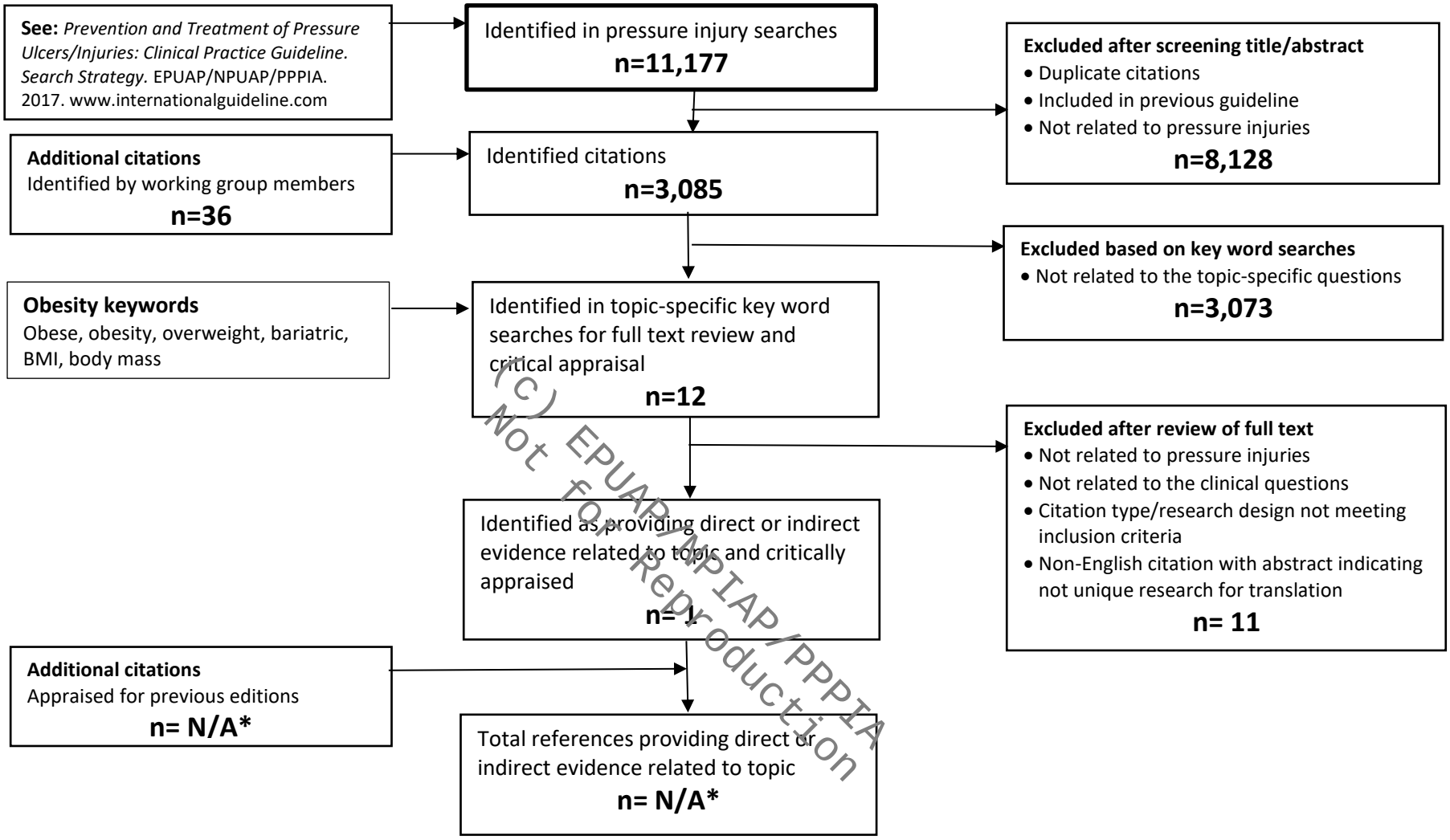
Individuals with obesity: data extraction and appraisals

Search results for 2019 International Pressure Injury Guideline: Individuals with obesity



* Recommendations related to all special populations are included in the topics to which the recommendation relates (e.g. support surfaces), and the references supporting these recommendations are included in the search reports for those topics.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Articles Reviewed for International Pressure Injury Guideline

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resources and are not for reproduction.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
Risk of pressure injury							
Hyun et al., 2014	Retrospective cohort study examining the incidence of PU in individuals who differ in BMI and to determine whether inclusion of BMI enhanced use of Braden scale in prediction of PUs	Participants were recruited in multiple ICU over a 3-year period in the USA (n=2632) **Inclusion criteria** • admitted to ICU for greater than 3 days • 18 yrs and older **Exclusion criteria** • PI present on admission **Participant characteristics** • 54.5% male • 81% white skinned, 15% dark skinned • 7.5% underweight, 17.9% normal weight, 48.5% obese, 26.1% extremely obese • No difference between normal and underweight individuals in age,	N/A	**Univariate analysis** • Age (p=0.42) • Sex (p=0.63) • Race/ethnicity white vs non-white (p=0.76) • Weight in lbs (weight higher in group with PI vs those without PI, p<0.001) • Length of stay measured as days in ICU (longer LOS in group with PI vs those without PI, p=0.04) • Braden total score on admission (lower in group with PI versus those without PI, p<0.001)	**Rate of pressure injures** • Overall rate of PU 5.6% • BMI <19: 8.6% • BMI 19 to 25: 5.5% • BMI 25 to 40: 2.8% • BMI >40 9.9%: **Multivariable analysis** • Normal versus underweight OR 0.62 (95% CI 0.33 to 1.17, p=0.14) • Normal versus obese OR 2.02 (95% CI 1.21 to 3.38, p=0.008) • Normal versus extremely obese OR 0.53 (95% CI 0.33 to 0.85, p=0.009) • Underweight versus obese OR 3.26 (95% CI 1.79 to 5.91, p<0.001) • Underweight versus extremely obese OR 0.27 (95% CI 0.18 to 0.40, p<0.001) • Braden total score scale and BMI category were predictors of the likelihood of PI ○ Extremely obese 3.7 x more likely to have a PI than obese, and 1.9 x more likely than normal weight individuals. ○ Underweight 3.3. x more likely to have a PI than obese individuals. ○ Normal weight 2x more likely to have a PI than obese individuals.	• Retrospective data collection relying on electronic records • Could not identify when PI occurred • Does not state how presence of PI assessed • Could not calculate BMI if height not available • Nil conflict of interest	**Level 3 (prognostic study)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
		gender or length of stay in ICU • Underweight individuals had lower total score on Braden than normal weight individuals (p=0.003)			**Author conclusions: BMI and incidences of PI were related in ICU patients, with underweight and extremely obese individuals at higher risk for PI than normal weight or obese individuals**		
Organisation and staffing issues							
Walden et al., 2013	Pre/post study **reporting outcomes from a comprehensive manual handling intervention aimed at decreasing pressure injuries and staff injuries**	Intervention was conducted in 6 wards in a hospital in US Inclusion criteria: • Patient weight was required to be > 200 pounds (91kgs) to use the intervention • Braden score ≤ 18 Exclusion criteria • Patients weighing less than 200 lbs • Braden score of higher than 18 or pressure injury present • Device related PIs not considered in analysis	• Mobilisation of patients was delegated to trained 'lift team' technicians working in pairs 24 hours/day with 7 day service • Lift team were screened, trained and competency tested • Lift teams assisted with safe turning, mobilization and moisture management for all individuals weighing > 200 pounds (91kgs) and Braden score ≤ 18 or pressure injury present	• Braden score was completed by nurses Occupational Health claim data was reviewed for injury rates • Staff satisfaction report • Does not specify the PI staging system used • Follow up: 1 year: compared results between 2 different years (pre and post intervention)	**Pressure injury outcomes** • There was a 43% decrease in non-device related Category/stage 3,and 4 and unstageable pressure injuries (p=0.039) **Other outcomes** • 38.5% decrease in patient handling related employee injuries • Improvements in nursing staff perception about workplace safety and satisfaction • Reduction in cost $493 293 of HA PI • Reduction in adverse events, improvement in quality for both patients and employees. The unique program serves as a foundation for other programs to think beyond the traditional boundaries and explore possibilities of linking programs aimed at enhancing employee outcomes with impact on enhancing quality of care	• No randomization or blinding • Uncertain how many people in each cohort and whether they were comparable • Uncertain if the facility implemented other indicatives that may have confounded the findings • Does not state how pressure injuries were assessed,by whom or how often • Differences in care and illness across units involved in the study • Fiscal analysis is debatable due to changes in cost/charge structures	**Level of evidence: 2** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
Support surfaces for preventing pressure injuries (note: some references also address treating pressure injuries)							
Levy, Kopplin, & Gefen, 2016	Computer modeling study evaluating the biomechanical effect of an air cell-based (ACB) cushion on tissues with increased fat mass (obese individuals) and individuals with diabetes.	No participants	**finite element computational modeling** • 10 variants were developed to assess biomechanical characteristics of sitting using ACB cushion • 5 variants were healthy individuals ranging in weight from normal BMI to different levels of obesity • 5 variants were individuals with the same weight categories plus diabetes as co-morbidity	• Runtime for each model variant was 7 to 32 hours	• Average strain and stress in fat tissues were mildly affected in healthy variant. • Variates using model of individual with diabetes showed pronounced effect on fat tissue strains. • Findings demonstrate that fat and skin tissues of an adult with diabetes is stiffer than in healthy adults. • ACB cushion could keep average strain and stress values from exceeding 20% increase in individuals with BMI of 30 (obese) **Author conclusion: The ACB cushion technology has the potential to protect tissues of individuals who are obese or have diabetes**	• One author works for company who sponsored research • Industry sponsored Not a human study	**Indirect evidence (computer modeling)**
Wiggermann, Smith, & Kumpar, 2017	Laboratory study exploring how much space individuals require when turning from supine to side lying as predicted by their anthropometric attributes	Participants were healthy volunteers with a range of BMI recruited in the USA (n=47) **Exclusion criteria** • Pregnant • Injury or condition which affects person independently get out of bed or roll on side	All individuals (n=47) performed turning on two surfaces while movement monitored on motion capture system: • Wore their own form fitting clothes • All surfaces 127cm (50inches) wide • Hard surface – rigid polyethylene surface • Soft surface – Compella™ bariatric	**Individuals were categorized according to BMI** • BMI 18.5 to 24.9 kg/m^2 • BMI 25 to 34.9 kg/m^2 • BMI 35 to 44.9 kg/m^2 Analysis of relationship between turn distance, a range of anthropometric variables, and surface type	**Predictors of space required to turn** • BMI was significantly correlated with distance required to turn to one side (adjusted R^2=0.88, p<0.001) • BMI was significantly correlated with distance required to turn to from one side to the other (adjusted R^2=0.86, p<0.001). • Waist circumference is best predictor of distance required to turn to one side (R^2=0.91) and distance required to turn to from one side to the other (R^2=0.88) • Although significant, the difference in space required to turn between hard and soft surface was only 0.5cm	• Based on healthy participants in laboratory setting • Participants had no condition precluding ability to self-position in bed • Does not measure influence of bed space on PI incidence • Industry sponsored, and researchers employed by industry	**Indirect evidence (PI not an outcome measure)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
		Participant characteristics 5 female and 5 male in each BMI category	bed with therapeutic air mattress • Standardized turning movement used for rolling (not dragging or repositioning hips) • Four trials per condition, turning to one side (single turn distance) or from one side to the other (double turn distance)		**Author conclusions: Individuals unable to self-reposition with a BMI <35 kg/m² require a 91cm (36in) wide bed, individuals unable to self-reposition with a BMI <40 kg/m² require a 102cm (40in) wide bed, and individuals unable to self-reposition with BMI ≥40 kg/m² require a 127cm (5-in) wide bariatric bed.**		
Pemberton, Turner, & VanGilder, 2009	Observational pilot study	Participants were a convenience sample of consecutively admitted patients (n=21) Inclusion: • BMI > 35 • Weight 250 to 500lbs • minimum 3 day stay on support mattress (max 7 days) Exclusion: • Using only one turning position Participant characteristics: • mean BMI 51.4 (±10.3) • mean age 51.7 years (±14, range 32 to 76) • 28% (n=6) had existing PU • 62% had COPD • 63% had hypertension	Low-air-loss, continuous lateral rotation bariatric bed with advanced microclimate technology (TotalCare® Bariatric Plus Therapy System) Participants spent an average of 4.8±2.5 days (range 2 to 8) on the bed surface.	• PU incidence • PU stage (NPUAP criteria) and size • employee satisfaction on a 4-point Likert scale • patient comfort rating (multiple choice questionnaire where 1 = very uncomfortable and 4 = very comfortable) Final outcome measures at day 7	• No new PUs developed • PUs decreased from an average size of 5.2 cm² (±5.2) to 2.6cm² (±5.0) • 5 PUs completely healed, but 3 PUs had no change • Mean caregiver satisfaction rating was 3.6 • Mean patient comfort rating 3.9 **Study conclusion: In patients with a BMI above 35kg/m², a low air loss, continuous rotation bariatric bed was associated with no new PUs and a decrease in PU size for existing PUs after a maximum of 7 days.**	• Small, non-randomised study • No statistical significance reported • No comparison group • No long term follow up (patients stayed on bed for between 2 and 7 days) •	**Level of evidence: 4** **Quality: low** *N.b.: includes some data relevant to treatment of pressure injuries*

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
		• 57% diabetes mellitus • 57% urinary incontinence • 43% faecal incontinence • 43% neurological impairment					
Elsner & Gefen, 2008	Biomechanical modelling to determine if internal muscle tissue loads under the ischial tuberosities (IT) is elevated at high BMI	• n=5 finite element (FE) models representing the same individual at BMIs ranging from 25.5 to 40	• Biomechanical models of internal muscle tissue loads under the IT in seated positions • Models represented the same individual (i.e. same IT shape, size, distance between IT), a 28 yr old male of 1.82m height, but with different thickness of gluteal muscles and fat tissue layers for different BMI In some models gluteal muscle atrophy of 30% was investigated to represent a patient with SCI	Computational FE models	• Maximal principal strain, compression strain, principle tensile stress, maximum shear stress and strain energy densities all increased with an increase in BMI • Increases were of a greater magnitude for seating on a hard surface versus a soft chair • When muscle atrophy was included in models (30% atrophy and a BMI of 40) there was additional increase in tensile stress, maximum shear stress and strain energy density.	• No simulation for BMI >40 • Does not provide evidence that increased tissue loading increases PU •	**Indirect evidence (lab modelling)**
Sopher, Nixon, Gorecki, & Gefen, 2010	Biomechanical modelling to determine if internal muscle tissue loads under the ischial tuberosities (IT) is elevated at high BMI	• n=21 finite element (FE) models representing the same individual at BMIs ranging from <16.5 to 40 • overweight (BMI 25 to 30) n=4 models • obese class I (BMI 30 to 35) n=1 model	• Biomechanical models of internal muscle tissue loads under the IT in seated positions • Models represented the same individual (i.e. same IT shape, size, distance between IT) but with different thickness of	• Computational FE models	• Percentage volume of muscle tissue exposed to critical compression strain increased 5.7 times for an increase in BMI from 19 to 40. • Trend of progressive increase in internal tissue loading for BMI outside the range 17 to 22.	• Unclear how model differentiated gluteal muscle density versus fat and influence on the findings • No simulation for BMI >40 • Does not provide evidence that increased tissue loading increases PU	**Indirect evidence (lab modelling)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
		• obese class II (BMI 35 to 40) n=2 models	gluteal muscles and fat tissue layers for different BMI				
Background prevalence information							
Rimmer, Yamaki, Lowry, Wang, & Vogel, 2010	Prospective web-based prevalence survey	n=461 adolescents (aged 12 to 18 years) with cognitive (n=322) or physical (n=139) disability based in the community overweight (BMI ≥ 85th percentile): • 130/322 with cognitive disability • 28/139 with physical disability 67.5% males (mean age 14.8±1.9) 32.5% females (mean age 15.2±2.0) •	• N/A	• Clinical trial	**Prevalence** • 1.8% of overweight adolescents with cognitive disability had PU versus 0.7% of healthy weight (p=0.574) • 30.8% of overweight adolescents with physical disability had PU versus 14.3% of healthy weight (p=0.081)	• Parent-reported web-based survey • Non-representative population – primarily higher SES • Unclear how parents differentiated PU from other wounds or if only health professional diagnosis was requested	**N/A**
Rana et al., 2009	Retrospective record analysis cohort study	n=1314 record reviews of children admitted to one paediatric hospital in USA admitted to trauma centre from Jan 2004 to July 2007. Inclusion: • Admission for a trauma injury • Documented weight and height Obese (n=294)	• N/A	• Database study	**Incidence** • PU occurred more often during the admission for obese population compared with non-obese population, (1% versus 0.2%, p=0.04) • Length of hospital stay did not differ between groups (2.6±5.0 days for non-obese versus 2.9±10 days for obese, p=0.50) and mortality was equivalent between groups.	• Database review for which 73% of entries did not have a documented weight so were not included • Single site study • Does not state how PU was classified • Did not appear to address PU present on admission • Comorbidity on admission was not reported (e.g. other risk factors such as	**N/A**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
		• BMI ≥95th percentile for age • Mean BMI 29.7 (significantly higher than non-obese group, p<0.001) • No differences between groups in reason for trauma admission • Both groups primarily female (approx. 70%) Non-obese (n=1020) • BMI <95th percentile for age Mean BMI 18.8				SCI were not controlled for)	
VanGilder, MacFarlane, Meyer, & Lachenbruch, 2009	Prospective web-based cross-sectional cohort survey with a convenience sample	Facilities in the US signed up for the survey and completed data on all patients admitted or residing in the facility within the 24 hour time period Acute, long term care, rehabilitation and home care. Prevalence rates by facility type are reported in study (without breakdown by weight) • 2006 702 facilities, n=88 743 • 2007 628 facilities, n=79 193	• N/A	• N/A	**Prevalence** Findings were very similar between 2006 data and 2007 data. Braden score was used for PU risk. **Under weight (BMI <18.5)** 5.5% of participants Mean Braden scale 16 Nosocomial PU 10.5% Stage I PU 32.8% Stage II 31.8% Stage III 7.5% Stage IV 9.4% Unstageable 13.6% DTI 4.6% **Normal (BMI 18.5 to 24.9)** 30.6% of participants Mean Braden scale 18 Nosocomial PU 7.8% Stage I PU 32.6% Stage II 36% Stage III 8%	• Facilitated and sponsored by a product manufacturer • Self reported data by facilities who chose to participate or not selection bias may have occurred as only facilities with a strong PU management ethos are likely to participate • Unclear how many incomplete records • No information about PU management in the facilities.	**N/A**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
					Stage IV 6.8% Unstageable 12.7% DTI 3.2% **Over weight (BMI 25 to 29.9)** 28.2% of participants Mean Braden scale 18 Nosocomial PU 5.8% Stage I PU 31.9% Stage II 37.2% Stage III 6.9% Stage IV 6.8% Unstageable 11.8% DTI 3.9% **Obese (BMI 30 to 39.9)** 25.9% of participants Mean Braden scale 18 Nosocomial PU 4.9% Stage I PU 30.8% Stage II 39.8% Stage III 5.4% Stage IV 6.9% Unstageable 11.6% DTI 4.2% **Extremely obese (BMI 40 to 49.9)** 7% of participants Mean Braden scale 18 Nosocomial PU 4.9% Stage I PU 26.2% Stage II 40.4% Stage III 7.6% Stage IV 6.1% Unstageable 15% DTI 3.4% **Super obese (BMI≥50)** 2.8% of participants Mean Braden scale 18 Nosocomial PU 5% Stage I PU 18.7% Stage II 51.2% Stage III 9.4% Stage IV 3.9% Unstageable 12.3%		

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	Level of evidence
					DTI 3.9% • Participants with BMI≥40 had significantly less stage I PU (p=0.02) and significantly more stage II PU (p=0.004) than participants with BMI<40		
Cai, Rahman, & Intrator, 2013	Prospective cohort study	Participants were newly admitted (from 2004 to 2008) nursing home residents in US followed for up to one year (n=2.217 million participants)	• N/A	• Database study	Prevalence of PU as determined from MDS database information **Moderate or severe obesity (BMI ≥ 35)** (7.7% population) • PU at time of admission : 24.03% • OR of having a PU on admission from residents who stayed at least 90 days OR=1.158 (95% CI 1.142 to 1.174, p<0.001) • OR of developing a PU for residents who had no PU on admission and stayed at least 90 days OR=1.192 (95% CI 1.171 to 1.214, p<0.001) **Mild obesity (BMI 30 to 35)** (11.6% population) • PU at time of admission :18.70% • OR of having a PU on admission from residents who stayed at least 90 days OR=1.032 (95% CI 1.020 to 1.045, p<0.001) • OR of developing a PU for residents who had no PU on admission and stayed at least 90 days OR=1.032 (95% CI 1.017 to 1.047, p<0.001) **No obesity (BMI 18.5 to 30)** (80.6% population) • PU at time of admission : 18.70% **Influences on OR of PUs in obese residents:** higher level of CAN staffing associated with lower level of PUs	• Database review which may have been inaccurate • Only considered residents who are "long stayers"	**N/A**

Table 1: Level of Evidence for Intervention Studies

Level 1	**Experimental Designs** • Randomized trial
Level 2	**Quasi-experimental design** • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	**Observational-analytical designs** • Cohort study with or without control group • Case-controlled study
Level 4	**Observational-descriptive studies (no control)** • Observational study with no control group • Cross-sectional study • Case series (n=10+)
Level 5	**Indirect evidence**: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.
Level 2	Non-consecutive studies or studies without consistently applied reference standards.
Level 3	Case-control studies or poor or non-independent reference standard.
Level 4	Mechanism-based reasoning, study of diagnostic yield (no reference standard).

Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	A prospective cohort study.
Level 2	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
Level 3	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS

Each criteria on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria

PROGNOSTIC STUDIES INCLUDING RISK FACTORS

	Author/year	Adequate description of baseline characteristics	Satisfactory study attrition	Clear outcome measures/prognostic factors	Range of prognostic factors/confounders measured identified and	Method of measuring prognostic factor is reported, valid and reliable	Same method of measure of prognostic factor for all	Continuous variables or appropriate cut offs	Percent participants with complete data acceptable	Appropriate imputation method	Confounders/prognostic factors accounted for in analysis	Selective reporting avoided	Adequate sample size (10 PIs per factor)	Level of evidence	Quality
2962	Hyun et al., 2014	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Level 3 (prognostic)	High

QUASI EXPERIMENTAL STUDIES

	Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
6133	Walden et al., 2013	Y	N	Y	U	U	N	Y	NA	N	N	2	Low

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